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L5: Entry 6 of 19 File: PGPB Jul 21, 2005

DOCUMENT-IDENTIFIER: US 20050158406 A1
TITLE: Methods for treating joint inflammation

Summary of Invention Paragraph:
[0010] In recent years NSAIDS (non-steroidal anti-inflammatory drugs), such as phenylbutazone, have been used to eliminate, diminish, or at least assist in managing the lameness in performance horses in all aspects of the horse industry (including racing, cutting, reigning, hunter-jumper, dressage, rodeo, barrel-racing). Unfortunately, NSAIDS require prescriptions and/or veterinary dispensing, are costly, and are accompanied by mild severe, and sometimes even catastrophic side effects.

Brief Description of Drawings Paragraph:
[0039] FIG. 2 illustrates the effect of formulations used in methods of this invention versus other commercially available treatments/NSAIDs on lameness of horses. The graph measures soundness score (measurement of lameness) after treatment with "bute", Cosequin, Absorbine Flex over 50 days.

Detail Description Paragraph:
[0132] The purpose of this study was to compare the various products, both available and non-available, alone or in combination with each other and against phenylbutazone, the "benchmark" NSAID for tissue inflammation reductions. In addition, videos of lame horses were taken on day #1, #21, and #50 for subjective evaluation. Looking for improvement in the lameness condition presented on day #1.

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L5: Entry 16 of 19 File: USPT Apr 4, 2000

US-PAT-NO: 6045827
DOCUMENT-IDENTIFIER: US 6045827 A

TITLE: Treatment of equine laminitis

DATE-ISSUED: April 4, 2000

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
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US-CL-CURRENT: 424/485; 424/422, 424/449, 424/450, 424/484, 424/718, 424/78.05, 514/150, 514/151, 514/165, 514/166, 514/564, 514/567, 514/610, 514/611, 514/644, 514/645, 514/740, 514/741, 514/742

CLAIMS:

What is claimed is:

1. A topical composition for the treatment of equine laminitis comprising a fast acting nitric oxide (NO) donor and L-arginine (L-Arg) dispersed in a lipid-based carrier.

2. The composition of claim 1 which further comprises a non-steroidal anti-inflammatory drug (NSAID).

3. The composition of claim 1 in which said lipid-based carrier comprises a membrane forming lipid.

4. The composition of claim 3 in which said membrane forming lipid comprises a phosphatidyl choline.

5. The composition of claim 4 in which said phosphatidylcholine comprises a natural or synthetic lecithin.

6. The composition of claim 1 in which said lipid-based carrier comprises at least one membrane forming lipid, at least one first biocompatible aliphatic organic solvent comprising 8-50 carbon atoms, at least one second hydroxyl group containing aliphatic organic solvent comprising 1-8 carbon atoms and at least one surfactant.

7. The composition of claim 1 in which said fast acting NO donor is selected from the group consisting of nitroglycerin, hydroxylamine, a nitrite, a nitroprusside, an azide, or a salt thereof.

8. The composition of claim 2 in which said NSAID is derived from acetic acid, propionic acid, butyric acid, or salicylic acid.

9. The composition of claim 2 in which said NSAID is derived from an aminoarylcarboxylic acid, arylcarboxylic acid, arylacetic acid, arylpropionic acid, arylbutyric acid, pyrazoles, pyrazolones, or thiazinecarboxamides.

10. The composition of claim 2 in which said NSAID is selected from the group consisting of ketoprofen, ibuprofen, or naproxen.

11. The composition of claim 1 which comprises about 0.5 to 3% by weight nitroglycerin and about 5 to 25% by weight of L-Arg, based on the weight of the total composition.

12. The composition of claim 1 which comprises about 1 to 2.5% by weight nitroglycerin and about 15 to 20% by weight of L-Arg, based on the weight of the total composition.

13. The composition of claim 1 which comprises a fast acting NO donor and a slow acting NO donor in a weight ration ranging from about 1:5 to about 1:50 for the total composition.

14. The composition of claim 2 which further comprises up to about 10% by weight of a non-steroidal anti-inflammatory drug (NSAID), based on the weight of the total composition.

15. The composition of claim 2 which comprises an NSAID and a slow acting NO donor in a weight ratio ranging from about 1:1.5 to about 1:5 for the total composition.

16. The composition of claim 1 which is an ointment, emulsion, creme, gel, or foam.

17. The composition of claim 16 that permits the delivery of said fast acting nitric oxide donor and L-Arg through the hoof, skin, or both of an affected equine.

18. A topical composition for the amelioration of the negative effects of equine laminitis comprising at least one fast acting nitric oxide (NO) donor, L-Arg and at least one NSAID dispersed in a lipid-based carrier comprising at least one membrane forming lipid, at least one first biocompatible aliphatic organic solvent comprising 8-50 carbon atoms, at least one second hydroxyl group containing aliphatic organic solvent comprising 1-7 carbon atoms and at least one surfactant.

19. A process for the preparation of a combination, which can be applied topically to alleviate the adverse effects of equine laminitis, comprising:

(a) combining a first mixture comprising at least one alcoholic solvent, at least one fast acting nitric oxide (NO) donor, at least one slow acting NO donor and at least one NSAID with a second mixure comprising at least one membrance forming lipid and at least one biocompatible organic solvent;

(b) admixing to the resulting mixure of step (a) an amount of a third mixure comprising water and a surfactant effective to provide a combination having a creamy texture.

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L5: Entry 18 of 19 File: USPT Apr 6, 1999

DOCUMENT-IDENTIFIER: US 5891472 A
TITLE: Treatment of equine laminitis

Abstract Text (1):
Compositions and methods of the topical treatment of equine laminitis are disclosed. In particular, combinations of a fast acting nitric oxide (NO) donor, a sustained acting NO donor and an NSAID mixed in a lipid-based carrier are described. The application of such combinations to the affected areas, e.g., the hoofs and surrounding tissues, of an equine afflicted with laminitis provides relief from the debilitating effects of this painful, often life-threatening condition.

Brief Summary Text (19):
In accordance with the invention, a topical composition for the treatment of equine laminitis is described comprising a fast acting nitric oxide (NO) donor, preferably nitroglycerin, and a sustained acting NO donor, preferably L-arginine (L-Arg), dispersed in a lipid-based carrier. In a preferred embodiment of the invention, the topical composition further comprises a non-steroidal anti-inflammatory drug (NSAID). The lipid-based carrier comprises preferably a membrane forming lipid, such as a phosphatidylcholine (e.g., a naturally occurring, naturally derived, synthetic, or semi-synthetic lecithin). Preferably, the topical combination is in the form of an ointment, emulsion, creme, gel, or foam that permits the delivery of the active ingredients of the fast acting nitric oxide donor and L-Arg through the hoof, skin, or both of an affected equine.

Brief Summary Text (20):
The invention also relates to a method of ameliorating the adverse effects of equine laminitis. The method, broadly contemplated, comprises topically administering to the affected areas of an equine an effective amount of a fast acting nitric oxide (NO) donor dispersed in a lipid-based carrier. In a preferred embodiment, the method further comprises topically administering to the affected areas an effective amount of a sustained acting NO donor. Most preferably, the method even further comprises topically administering to the affected areas an effective amount of a non-steroidal anti-inflammatory drug (NSAID). The foregoing active ingredients can be administered in any sequence (i.e., sequentially) or substantially at the same time period (i.e., contemporaneously).

Brief Summary Text (22):
The present invention also contemplates a process for the preparation of a combination, which can be applied topically to alleviate the adverse effects of equine laminitis, comprising: (a) combining a first mixture comprising at least one alcoholic solvent, at least one fast acting nitric oxide (NO) donor, at least one sustained acting NO donor and at least one NSAID with a second mixture comprising at least one membrane forming lipid and at least one biocompatible organic solvent; (b) admixing to the resulting mixture of step (a) an amount of a third mixture comprising water and a surfactant effective to provide a combination having a creamy texture.

Detailed Description Text (9):
As described above, the present invention is directed to a topical composition for

the treatment of equine laminitis. In a particular embodiment of the invention, the topical composition comprises a fast acting nitric oxide (NO) donor and a sustained acting NO donor. In a preferred embodiment, the topical composition further comprises a non-steroidal anti-inflammatory drug (NSAID). For maximizing the effectiveness of the topical composition of the present invention, the active ingredients, such as nitroglycerin, L-Arg and ketoprofen (a fast acting NO donor, a sustained acting NO donor and an NSAID, respectively) are dispersed, optionally with other active or non-active ingredients, thickeners, emollients, fillers, etc., are dispersed in a lipid-based carrier.

Detailed Description Text (16):
Hence in a particular embodiment a topical composition is provided for the amelioration of the negative effects of equine laminitis comprising at least one fast acting nitric oxide (NO) donor, L-Arg and at least one NSAID dispersed in a lipid-based carrier comprising at least one membrane forming lipid, at least one first biocompatible aliphatic organic solvent comprising 8-50 carbon atoms, at least one second hydroxyl group containing aliphatic organic solvent comprising 1-8 carbon atoms and at least one surfactant.

Detailed Description Text (18):
The present invention is directed to a method of alleviating or ameliorating the adverse or negative effects of equine laminitis. Generally, the desired method comprises topically administering to the affected areas of an equine an effective amount of a fast acting nitric oxide (NO) donor dispersed in a lipid-based carrier. Other methods of increasing desirability include the topical administration to the affected areas an effective amount of a sustained acting NO donor and, also, the topical administration to the affected areas an effective amount of a non-steroidal anti-inflammatory drug (NSAID). Preferably, a topical composition containing a fast acting NO donor, a sustained acting NO donor and an NSAID is applied daily for a period of at least about a few weeks (e.g., for at least about one week, two weeks, three weeks, or four weeks) to a few months (e.g., for at least about one month, two months, or three months) to the affected areas of the equine. It is important to point out, however, that each of the principal active ingredients can be topically administered sequentially or more or less contemporaneously. Also, the topical composition can be applied once daily or more than once, for example, twice daily or as needed.

Detailed Description Text (21):
In a specific embodiment of the invention a method is provided of ameliorating the adverse affects of equine laminitis which comprises topically administering at least once daily to the affected areas of an equine an effective amount of a combination comprising at least one fast acting NO donor, L-Arg and at least one NSAID in a lipid-based carrier; and continuing to administer said combination until the equine exhibits signs of recovery. Such signs of recovery include but are not limited to regaining the ability to stand, improved posture, normal gait, improved appetite, or improved or stabilized organ function. Still other signs may be obtained from performing blood tests on the affected equine, including a horse, pony, donkey, ass, zebra and the like. For example the blood test could show normal creatinine or blood urea nitrogen levels, where these levels would be elevated in ill equines.

Detailed Description Text (23):
The present invention is also directed to a process for the preparation of a combination, which can be applied topically to alleviate the adverse effects of equine laminitis. In particular, the topical combination or composition is obtained by first preparing a first mixture comprising at least one alcoholic solvent, at least one fast acting nitric oxide (NO) donor, at least one sustained acting NO donor and at least one NSAID. A second mixture is then prepared, which comprises at least one membrane forming lipid and at least one biocompatible organic solvent. The first and second mixtures are then combined with mixing, preferably at or

slightly below room temperature.

Detailed Description Text (29):
It is considered to be within the scope of this invention to provide additional therapeutic agents in the topically applied composition hereof in order to treat specific conditions that often accompany equine laminitis. This condition is painful. It is therefore appropriate to include topical anesthetics in the inventive compositions. Topical analgesics are suitable constituents as well. NSAIDs, such as ketoprofen and naproxen, are useful additions to the creme and/or ointment compositions of this invention. Further, thickening agents are a useful part of the compositions of this invention. Hydroxymethyl or hydroxyethyl cellulose and the like can be used as thickening agents.

Detailed Description Text (36):
Nitroglycerin and L-Arg have been specified as the active ingredients of the compositions of this invention. It will be understood that nitroglycerin is a fast acting NO donor, an immediate vasodilator, while L-Arg must first be converted to NO before it becomes effective. Therefore, the L-Arg has a more sustained release. Other immediate and sustained release sources of NO are believed effective in combating equine laminitis by means of a topically applied composition comprising combinations described herein. The compounds that appear to be comparable to nitroglycerin and L-Arg, in that they have known tendency to release NO either rapidly/immediately, or slowly/sustained, respectively, are described herein. Others may be apparent to those of ordinary skill in the art given the descriptions provided herein. Thus, other vasodilators, such as isoxsuprine or nitroprusside may be substituted for nitroglycerin. Other NSAIDs may be substituted for the ketoprofen, such as phenylbutazone, aspirin, flurixin, ibuprofen and naproxen. Slow/sustained acting NO releasing materials, which have similar activity to L-Arg, may also be apparent to those of ordinary skill in the art considering the description presented herein.

CLAIMS:

12. A method of ameliorating the adverse effects of equine laminitis which comprises topically administering at least once daily to the affected areas of an equine a combination comprising at least one fast acting NO donor at least one slow acting donor, L-Arg, and at least one NSAID in a lipid-based carrier; in an amount sufficient to promote signs of recovery, said recovery comprises regaining the ability to stand, improved posture, normal gait, improved appetite, or improved or stabilized organ function.

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